

**REMARKS**

Claims 1-20 are pending. The Examiner restricted the pending claims into a first set of 8 groups as indicated on page 2 of the Office Action, and a second set of 2 groups as indicated on page 3 of the Office Action. Applicants hereby provisionally elect Group II (claims 3-6, 9-11, 12-14), drawn to a polynucleotide encoding a polypeptide, vectors, host cells expressing the polynucleotide, and methods of expressing the polynucleotide, and Group A, drawn to SEQ ID NO: 3 or a sequence encoding SEQ ID NO: 1, for examination **with traverse**.

In this regard, Applicants draw the Examiner's attention to Section 803.04 of the Manual of Patent Examining Procedure. While contending that nucleotide sequences that encode different proteins "constitute independent and distinct inventions" the Commissioner has decided to "permit a reasonable number of such nucleotide sequences to be claimed in a single application" so as to "further aid the biotechnology industry in protecting its intellectual property." To this end, the Patent Office "determined that normally ten sequences constitute a reasonable number for examination purposes" and that that number does not create "an undue burden on the Office." Indeed, the Office states that "up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction." Accordingly, the Examiner's contention that SEQ ID NOs: 3 and 4 are "distinct from the other" and, therefore, subject to restriction, is not consistent with Office practice.

Indeed, under the "Examples of Nucleotide Sequence Claims" subsection of Section 803.04, the Office states that "[O]nly the ten nucleotide sequences selected in response to the restriction requirement and any other claimed sequences which are patentably indistinct therefrom will be examined" (emphasis added).

For this reason, Applicants contend that Group A, drawn to polynucleotides depicted in SEQ ID NO: 3, should be examined alongside Group B, drawn to polynucleotides depicted in SEQ ID NO: 4. Accordingly, Applicants kindly request that the Examiner rejoin Groups A and B and examine SEQ ID NOs: 3 and 4 together.

Applicants also traverse this restriction requirement on the grounds that the unity of invention standard must be applied in national stage applications. Section 1850 of the Manual of Patent Examining Procedure (original 8th edition, published August, 2001) (hereinafter "MPEP") provides:

... [W]hen the Office considers international applications ... during the national stage as a Designated or Elected Office under 35 U.S.C. 371, PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C. 111....

In applying PCT Rule 13.2 to ... national stage applications under 35 U.S.C. 371, examiners should consider for unity of invention all the claims to different categories of invention in the application and permit retention in the same application for searching and/or preliminary examination, claims to the categories which meet the requirements of PCT Rule 13.2....

*Id* at page 1800-60 to -61.

MPEP section 1893.03(d) reiterates the Examiner's obligation to apply the Unity of Invention standard PCT Rule 13.2 instead of U.S. restriction/election of species practice:

Examiners are reminded that unity of invention (not restriction) practice is applicable ... in national stage (filed under 35 U.S.C. 371) applications.

*Id* at page 1800-149, column 1.

Indeed, according to Example 17, Part 2 of Annex B to the PCT Administrative Instructions, the Examiner is obliged to find that "[T]he protein and the DNA sequence

exhibit corresponding special technical features” and that, therefore, there is no lack of unity between claims directed to a protein “X” and the DNA sequence that encodes protein “X.”

Thus, in the present case, unity of invention does exist at least as between claims 1, 2 and 15 (Group I) and claims 3-6, 9-11, and 12-14 (Group II), which cover the polypeptide depicted in SEQ ID NO: 1, and the DNA depicted in SEQ ID NO: 3, which encodes that polypeptide. Accordingly, Applicants respectfully request that the Examiner also rejoin Groups 1 and 2, and examine their respective claims in a single application.

The Examiner is invited to contact the undersigned if it is felt that a telephone interview would expedite prosecution.

Respectfully submitted,

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